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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|-------------------------|
| 10/035,918 | 12/28/2001 | Rajiv Shah | 047711-0293 | 2208 |
| 7590 | 06/02/2004 | | | EXAMINER PAK, YONG D |
| Irvin C. Harrington, III FOLEY & LARDNER 35th Floor 2029 Century Park East Los Angeles, CA 90067-3021 | | | ART UNIT 1652 | PAPER NUMBER |
| DATE MAILED: 06/02/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/035,918 | SHAH ET AL. | |
| | Examiner Yong D Pak | Art Unit 1652 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 March 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3-8 and 10-54 is/are pending in the application.
- 4a) Of the above claim(s) 25-43 and 48-54 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1, 3-8, 10-24 and 44-47 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

The amendment filed on March 22, 2004, amending claims 1, 3, 4, 6 and 8 and adding claims 44-54, has been entered.

Claims 1, 3-8 and 10-54 are pending.

Election/Restrictions

Claims 25-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

Newly submitted claims 48-54 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 48-54 are drawn to a method of making a biosensor which is patentably distinct from the method of Group I and III. The methods have different utilities and effects.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 48-54 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

Response to Arguments

Applicant's arguments filed on March 22, 2004 have been fully considered but they are not persuasive.

Claims 1, 3-5, 19-24 and 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wohlfahrt et al. in view of Kenan et al.

Applicants argue that Wohlfahrt et al. and Kenan et al. in combination do not teach a method of measuring concentration of glucose oxidase. The examiner disagrees.

Kenan et al. teach that a library of colonies can be generated and protein expression libraries can be screen for functional properties, for example such as catalysis (cDNA Libraries, page 2). In order to screen for functional properties, one of ordinary skill in the art would recognize that the expressed protein is purified and its characterizations qualified, such as running gels, determining concentration of the protein through fluorescent techniques, performing enzymatic assays.

Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wohlfahrt et al. and Kenan et al. as applied to claims 1, 3-5 and 19-24 above, and further in view of Byalina et al.

Applicants argue that the combined teachings of Wohlfahrt, Kenan and Byalina do not teach a method of determining concentration of active glucose. The examiner

disagrees as discussed above. Applicants also argue that Bylina does not teach mutating a gene into a gene that is peroxide resistant. The rejection is made over the teachings of Wohlfahrt and Kenan. Wohlfahrt et al. and Kenan et al. in combination teach a method of generating libraries mutants galactose oxidase genes and screening for mutants that are resistant to oxidation by peroxidases (see full rejection in previous Office Action).

Claims 10-18 and 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wohlfahrt et al. and Kenan et al. as applied to claims 1, 3-5 and 19-24 above, and further in view of Shtelzer.

Applicants argue that the combined teachings of Wohlfahrt, Kenan and Shtelzer do not teach a method of determining concentration of active glucose. The examiner disagrees as discussed above.

Applicants argue that Shtelzer does not teach a method of using glucose oxidase resistant to peroxide. The rejection is made based on the combined teachings of Wohlfahrt, Kenan and Shtelzer. Wohlfahrt et al. and Kenan et al. in combination teach a method of generating libraries mutants galactose oxidase genes and screening for mutants that are resistant to oxidation by peroxidases (see full rejection in previous Office Action).

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong D. Pak
Patent Examiner

May 27, 2004



PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TELEPHONE (703) 308-3804
FAX (703) 872-9307